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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,935	10/30/2003	Sing Rong	15526 (PC23188A)	3803

23389 7590 08/22/2006

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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,935	RONG ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to isolated polynucleotides, vectors and host cells containing said polynucleotide, classified in class 536, subclass 23.1.

II. Claims 12-13, drawn to a transgenic organism, classified in class 800, subclass 10.

III. Claims 14 and 16-20, drawn to isolated polypeptides, classified in class 530, subclass 350.

IV. Claim 15, drawn to an antibody that specifically binds the polypeptide of SEQ ID NO: 21 or SEQ ID NO: 23, classified in class 530, subclass 387.1.

V. Claim 21-26, drawn to a method for treating an apoptosis-related disorder in a subject, classified in class 424, subclass 130.1.

VI. Claims 27-30, drawn to a method for identifying a compound which modulates expression of a TRAIL-encoding sequence, classified in class, 435, subclass 6.

VII. Claim 31-32, drawn to a method for identifying a compound which modulates activity of a TRAIL sequence product, classified in class, 435, subclass 7.21.

VIII. Claim 33-36, drawn to a method for modulating the expression of a TRAIL-encoding sequence in a cell, classified in class, class 424, subclass 94.1.

IX. Claim 33-36, drawn to a method for modulating the activity of a TRAIL-encoding sequence in a cell, classified in class class 424, subclass 178.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The polynucleotides of Group I, the transgenic animal of Group II, the polypeptides of Group III and the antibody of Group IV, are all structurally and chemically different from each other. A polynucleotide's structure is comprised of linear, contiguous nucleotides, an organism's structure is dependent on the structure of the cell or cells it contains, a polypeptides's structure is comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure, and while both polypeptides and antibodies are structurally related by virtue of their contiguous sequence of amino acids, they are distinct structures based on their distinct three-dimensional structures, wherein proteins fold into a variety of structures and antibodies maintain a specific, Y-shape. The polypeptide is made by translation of mRNA, the polynucleotide is made by nucleic acid synthesis, the transgenic organism is made by genetic recombination and the antibody is raised by immunization. Furthermore, the polypeptide can be used for methods of treatment, the polynucleotide can be used for hybridization screening, the transgenic organism can be used to produce recombinant polypeptides and the antibody can be used to purify the antigen, for example. The examination of all groups would require

different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-IV are patentably distinct.

The methods of Inventions of Groups V-IX differ in the method objectives, method steps and parameters. The invention of Group V recites a method for treating an apoptosis related disorder. The invention of Group VI recites a method for identifying a compound which modulates expression of a TRAIL-encoding sequence. The invention of Group VII recites a method for identifying a compound that modulates the activity of a TRAIL polypeptide. The invention of Group VIII recites a method for modulating the expression of a TRAIL-encoding sequence, wherein a compound that modulates the expression of a TRAIL-encoding sequence is administered to a cell. The invention of Group IX recites a method for modulating the activity of a TRIAL polypeptide, wherein a compound that modulates the activity of a TRAIL polypeptide is administered to a cell. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups V-IX are separate and distinct in having different method objectives, method steps, parameters, reagents used and different endpoints and are patentably distinct.

Inventions Group I and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the host cells comprising TRAIL-encoding polynucleotides of Group I could be used in a materially different process such as production of the TRAIL polypeptide, or the materially different process of identifying a compound that modulates the activity of a TRAIL polypeptide of Group VII, or the materially different process of modulating the expression of a TRAIL-encoding sequence of Group VIII, or the materially different process of modulating the activity of a TRIAL polypeptide of Group IX, which differ in the method objectives, method steps and parameters from the process of identifying a compound which modulates expression of a TRAIL-encoding sequence of Group VI and are therefore distinct.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

David Blanchard
AU 1643